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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,323	01/31/2002	Carl W. Gilbert	329.1001-U	9839

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LUCAS & MERCANTI, LLP
475 PARK AVENUE SOUTH
15TH FLOOR
NEW YORK, NY 10016

EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,323	GILBERT ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14,16,22,25 and 31-36* is/are pending in the application.

4a) Of the above claim(s) *13,15,17-21,23 and 26-30* is/are withdrawn from consideration.

5)☒ Claim(s) *32* is/are allowed.

6)☒ Claim(s) *1-12,14,16,22,24,25,31,33,35 and 36* is/are rejected.

7)☒ Claim(s) *34* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's arguments with respect to claims 1-12, 14, 16, 22, 25 and 31-36 have been considered but are moot in view of the new ground(s) of rejection.

The Status of Claims

Claims 1-12, 14, 16, 22, 25 and 31-36 are under consideration.

Claims 1-12, 14, 16, 22, 24-25 , 31, 33, and 35-36 have been rejected.

Claims 13, 15, 17-21, 23, and 26-30 are withdrawn from consideration.

Claim 32 is allowable.

Claim 34 is objected.

Claim 34 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 14, 16, 22, 25 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way to

convey reasonably to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 1, the phrase "

B is ~~a first active moiety, reactive group moiety or a polymer~~ selected from the group consisting of antibodies, antibody fragments, single chain antibodies, proteins, nucleic acids,

lectins, lipids, carbohydrates, peptides, hormones, ligands for receptors, growth factors, interferons, collagen, cytokines, metabolites that bind to a cell surface receptor, sugar peptides, inhibitors of cell surface enzymes, dextrans"

" is recited.

Each of those terms is a functional language without describing their concrete chemical structures. The claimed compound needs clearly outlined boundary of the compound; otherwise, it becomes the compound without any limit, which can not be claimed in the patent. The Claim does not contain a complete generic formula with the chemically identifiable B substituents, particularly.

According to the MPEP §2163 I. A. "the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described

in the specification and which is not conventional in the art or known to one of ordinary skill in the art." The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406." Applicants have disclosed some species , species of enzymes, the species of antibody, such as trastuzumab, and murine mAbs ,but have mostly made no assertion that there is any correlation between the biological functions of those claimed languages and their corresponding structures.

The Court of Appeals for the Federal Circuit held in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 at 1406. "[a] written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *In re*

Smythe, 480 F.2d 1376, 1383, *Fiers*, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Applicants' functional definitions in the claimed formula simply lack the precision required by the Court of Appeals for the Federal Circuit.

According to the MPEP §2163.02 Standard for Determining Compliance With the Written Description Requirement,

> "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed". *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter". *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In *re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983))."

Thus, those of ordinary skill in the art, who would use Applicants' compounds, would not know what each of the functional languages is meant for the particular compounds. That would not have understood the inventor to be in possession of the claimed invention at the time of filing.

This case was filed before Applicants had a clear idea of the structures of their desired compounds, how to make their compounds, and use the compounds made from them. The specification provides broad areas of future research and speculation, inviting undue experimentation in learning how to use Applicants' invention. Applicants may well now be developing practical applications of their invention, but the question here is what application they possessed at the time of filing. Anything is possible but as the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences wrote in *Bindra v. Kelly*, 206 USPQ 570 "*Probable* utility does not establish practical utility. Practical utility can, in our view, be established only by actual testing therefore, or by establishing such facts as would be convincing that such utility could be "foretold with certainty." *Blicke v. Treves*, supra, 112 USPQ at 475."

Applicants are reminded of what the U.S. Court of Appeals Federal Circuit wrote in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398, "In claims involving chemical materials, generic formulae usually indicate with specificity

what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). "It is only a definition of a useful result rather than a definition of what achieves that result." "The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.")".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 14, 16, 22, 25 , 31, and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

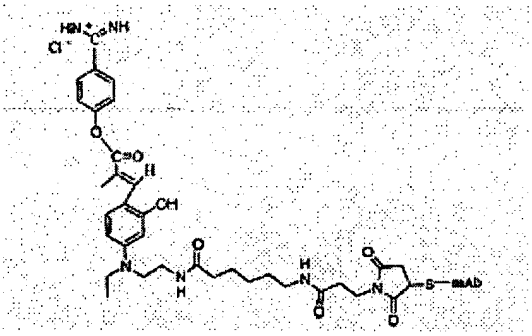
In claim 1 , the phrases "metabolites, polyethylene glycol polymers, polyalkylene oxides, glycosaminoglycans, poly-aspartic acid, poly-l-lysine, polyvinylprrolidone, polyglutamic acids, polyethylene glycol polymer derivatives" are recited. Each of the phrases "metabolites, polyethylene glycol polymers, polyethylene glycol polymer derivatives" is vague and indefinite.

Concerning the " metabolites", they are defined as the breakdown product of a physiologically active substance for example, a drug, produced by the body metabolism; however, the specification does not elaborate what the " metabolites" are in the compounds.

Concerning the polyethylene glycol polymers, polyalkylene oxides, glycosaminoglycans, poly-aspartic acid, poly-l-lysine, polyvinylprrolidone, polyglutamic acids, there are the definite upper and lower ranges of molecular weight for the polymers; however, the claim does not specify what the definite upper and lower ranges of molecular weight of the polymers are for the compounds.

Regarding the polyethylene glycol polymer derivatives, the specification does not elaborate what is meant by the terms "the polyethylene glycol polymer derivatives". Therefore , an appropriate correction is required.

In claim 22, the following compound is disclosed:



"mAb" is vague and indefinite because there is no concrete chemical formula for "mAb". The claimed compound needs to specify what the names of the monoclonal antibody are for the compounds. So far, we have various types of the monoclonal antibody available in the market as shown below:

- Transplant rejection
  - Muronomab-CD3[2], approved 1986 (first ever approval)
  - Daclizumab[3], approved 1997 L04AA08
  - Basiliximab[4], approved 1998 L04AA09
- Cardiovascular disease
  - Abciximab, approved 1994 B01AC13

- Cancer
  - Rituximab, approved 1997 L01XC02
  - Trastuzumab (Herceptin®), approved 1998 L01XC03
  - Gemtuzumab ozogamicin, approved 2000 L01XC05
  - Alemtuzumab, approved 2001 L01XC04
  - Ibritumomab tiuxetan, approved 2002 V10XX02
  - Cetuximab, approved 2004 L01XC06
  - Bevacizumab, approved 2004 L01XC07
- Viral infection
  - Palivizumab, approved 1998 J06BB16

- Inflammatory diseases
  - Infliximab, approved 1998 L04AA12
  - Eculizumab, approved 2000
  - Omalizumab, approved 2004 R03DX05
  - Efalizumab
  - Adalimumab

Therefore, an appropriate correction is required.

In claims 31, 35, and 36 , the phrase "reagent containing" is recited. The expression is vague and indefinite because the term "containing " does not exclude the presence of other ingredients than one or ones recited. Ex parte Muench , 79 USPQ 92 (PTO Bd. App. 1948). Therefore, an appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*** 5/12/06